

IN THE CLAIMS

Cancel claims 46 - 54 without prejudice and without disclaimer.

The pending claims shall read as follows:

1. A dosage form comprising a drug layer comprising 8 mg of hydromorphone, 67.8 mg of poly(ethylene oxide) of 200,000 molecular weight, 4 mg of poly(vinyl pyrrolidone), and 0.2 mg of a lubricant; a delivery layer comprising 37.8 mg of poly(ethylene oxide) possessing a 2,000,000 molecular weight, 18 mg of sodium chloride, 3 mg of hydroxypropylmethylcellulose of 9,200 molecular weight, 0.6 mg of a colorant, and 0.15 mg of a lubricant; a semipermeable wall comprising 27.2 mg of cellulose acetate of 39.8% acetyl content, and 0.275 mg of polyethylene glycol of 3,350 molecular weight; a passageway in the wall; and a controlled rate of release of 0.427 mg/hr for 17.3 hours.

2. A dosage form comprising 32 mg of hydromorphone, 119.6 mg of poly(ethylene oxide) possessing a 200,000 molecular weight, 8 mg of poly(vinyl pyrrolidone) of 42,000 molecular weight, and 0.4 mg of magnesium stearate; a delivery layer comprising 76.49 mg of poly(ethylene oxide) of 2,000,000 molecular weight, 36 mg of sodium chloride, 6 mg of hydroxypropylmethylcellulose of 9,200 molecular weight, 0.3 mg of magnesium stearate, 1.2 mg of a colorant, and 0.012 mg of an antioxidant; a semipermeable wall comprising 29.6 mg of cellulose acetate comprising an acetyl content of 39.8%, and 0.29 mg of polyethylene glycol possessing a

3,350 molecular weight, which wall surrounds the layers; a passageway in the dosage form; and a controlled rate of release of 1.811 mg/hr for 16.1 hours.

3. A dosage form comprising 64 mg of hydromorphone, 138.6 mg of poly(ethylene oxide) possessing a 200,000 molecular weight, 10.7 mg of poly(vinyl pyrrolidone) of 42,000 molecular weight, and 0.53 mg of a lubricant; a delivery layer comprising 104.53 mg of poly(ethylene oxide) of 2,000,000 molecular weight, 49.2 mg of an osmagent, 8.2 mg of hydroxypropylmethylcellulose of 9,200 molecular weight, 1.64 mg of a colorant, 0.41 mg of a lubricant, and 0.123 mg of an antioxidant; a semipermeable wall comprising 38.61 mg of cellulose acetate comprising a 39.8% acetyl content, and 0.39 mg of polyethylene glycol of 3,350 molecular weight, which wall surrounds the layers; a passageway in the wall; and a controlled rate of release of 3.77 mg/hr of hydromorphone over 15.3 hours.

4. A dosage form comprising 16 mg of hydromorphone, 135.6 mg of poly(ethylene oxide) of 200,000 molecular weight, 8 mg of poly(vinyl pyrrolidone) of 42,000 molecular weight, and 0.4 mg of a lubricant; a delivery layer comprising 76.49 mg of poly(ethylene oxide) of 2,000,000 molecular weight, 36 mg of an osmagent, 6 mg of hydroxypropylmethylcellulose of 9,200 molecular weight, 1.2 mg of a colorant, 0.3 mg of a lubricant, and 0.12 mg of an antioxidant; a semipermeable wall that surrounds the layers comprising 27.52 mg of cellulose acetate of 39.8% acetyl content, and 0.27 mg of

polyethylene glycol of 3,350 molecular weight; a passageway in the dosage form; and a controlled rate of release of 0.957 mg/hr for 15.0 hours.

5. A dosage form comprising: a drug layer comprising 8 mg of a member selected from the group consisting of hydromorphone and hydromorphone pharmaceutically acceptable salt, 84.70 wt% poly(ethylene oxide), 5 wt% poly (vinylpyrrolidone), 0.05 wt% butylated hydroxytoluene and 0.25 wt% magnesium stearate; an expandable layer comprising 63.675 wt% poly(ethylene oxide), 30 wt% of sodium chloride, 5 wt% of hydroxypropylmethylcellulose, 0.075 wt% of butylated hydroxytoluene, 1 wt% of a colorant, and 0.25 wt% of magnesium stearate; a semipermeable wall comprising 99 wt% cellulose acetate and 1 wt% polyethylene glycol that surrounds the drug and expansion layers; and, an exit in the wall for delivering hydromorphone from the dosage form.

6. The dosage form according to claim 5, wherein the drug layer comprises 16 mg of a member selected from the group consisting of hydromorphone and a pharmaceutically acceptable salt.

7. The dosage form according to claim 5, wherein the drug layer weighs 80 mgs.

8. The dosage form according to claim 6, wherein the drug layer weighs 160 mg.

9. The dosage form according to claim 5, wherein the expandable layer weighs 60 mg.

10. The dosage form according to claim 6, wherein the expandable layer weighs 120 mg.

11. The dosage form according to claim 5, wherein the dose of hydromorphone comprises 10 wt% of the drug layer.

12. The dosage form according to claim 6, wherein the dose of hydromorphone comprises 10 wt% of the drug layer.

13. The dosage form according to claim 5, wherein the expandable layer weighs 60 mg.

14. The dosage form according to claim 5, wherein the expandable layer weighs 120 mg.

15. A dosage form comprising: a drug layer comprising 32 mg of a member selected from the group consisting of hydromorphone and hydromorphone pharmaceutically acceptable salt, 74.75 wt% poly(ethylene oxide), 5 wt% poly(vinylpyrrolidone) and 0.25 wt% magnesium stearate, an expandable layer comprising 63.675 wt% poly(ethylene oxide), 30 wt%

sodium chloride, 5 wt% hydroxypropylmethylcellulose, 0.075 butylated hydroxytoluene, 1 wt% colorant, and 0.25 wt% magnesium stearate; a semipermeable wall comprising 99 wt% cellulose acetate and 1 wt% poly(ethylene glycol), which wall surrounds the drug and expandable layers; and, an exit in the wall for delivering hydromorphone from the dosage form.

16. The dosage form according to claim 14, wherein the drug layers weighs 160 mg.

17. The dosage form according to claim 14, wherein the expandable layer weighs 120 mg.

18. The dosage form according to claim 14, wherein the dose of hydromorphone is 20 wt% of the drug layer.

19. A dosage form for delivering orally hydromorphone to a patient in need of relief from pain, wherein the dosage form comprises: a drug layer comprising 64 mg of a member selected from the group consisting of hydromorphone and its pharmaceutically acceptable salt, 64.75 mg of a poly(alkylene oxide), 5 wt% of a poly(vinylpyrrolidone) and 0.25 wt% of a lubricant; an expandable layer comprising 63.675 wt% of a poly(alkylene oxide), 30 wt% of an osmotically effective solute, 5 wt% of a hydroxypropylalkylcellulose, 0.075 wt% of an antioxidant, 1 wt% of a colorant, and 0.25 wt% of a lubricant; a semipermeable wall that surrounds the layers

comprising 99 wt% cellulose acetate, and 1 wt% poly(ethylene glycol); and, an exit in the semipermeable wall for delivering the hydromorphone to the patient to provide relief from pain.

20. The dosage form according to claim 15, wherein the drug layer weighs 214 mg.

21. The dosage form according to claim 15, wherein the expandable layer weighs 164 mg.

22. The dosage form according to claim 15, wherein the dose of hydromorphone is 30 wt% of the drug layer.

23. A dosage form comprising a drug layer that weighs 80 mg and comprises 10.5% hydromorphone hydrochloride, 84.23% poly(ethylene oxide) having a 200,000 molecular weight, 5% poly(vinylpyrrolidone), 0.02% butylated hydroxytoluene, and 0.25% magnesium stearate; an expandable layer that weighs 60 mg and comprises 64.3% poly(ethylene oxide) possessing a 2,000,000 molecular weight, 30.00% sodium chloride, 5% hydroxypropylmethylcellulose, black iron oxide and lactose, 0.25% magnesium stearate, and 0.05 butylated hydroxytoluene; a membrane that surrounds the drug and expandable layers comprising 99% cellulose acetate and 1% polyethylene glycol; and an exit in the membrane for delivering the hydromorphone from the dosage form.

24. The dosage form according to claim 23, wherein the dosage form comprises 0.4% or 1% of black iron oxide and lactose.

25. The dosage form according to claim 23 on, wherein the poly(vinylpyrrolidone) comprises a molecular weight of 38,000 to 42,000, the hydroxypropylmethylcellulose comprises a molecular weight of 9,200 to 11,300, and the expandable layer weighs 54 to 66 mg.

26. The dosage form according to claim 23 wherein the cellulose acetate comprises a 39.8% acetyl content and the polyethylene glycol comprises a 3,350 to 4,000 molecular weight.

27. The dosage form according to claim 23, wherein the membrane is a wall and weighs 25 mg.

28. A dosage form comprising a drug layer that weighs 152.4 mg and comprises 10.5% hydromorphone hydrochloride, 84.23% poly(ethylene oxide) of 200,000 molecular weight, 5% poly(vinylpyrrolidone), 0.02% butylated hydroxytoluene, and 0.25% magnesium stearate; an expandable layer comprising 64.3% poly (ethylene oxide) possessing a 2,000,000 molecular weight, 30.00% sodium chloride, 5% hydroxypropylmethylcellulose, black iron oxide and lactose, 0.25% magnesium stearate, and 0.05% butylated hydroxytoluene; a membrane that surrounds the layer and

comprises 99% cellulose acetate and 1% polyethylene glycol; and an exit in the membrane for delivering the drug from the dosage form.

29. The dosage form according to claim 28, wherein the dosage form comprises 0.4% or 1% of black iron oxide and lactose.

30. The dosage form according to claim 28, wherein the poly(vinylpyrrolidone) comprises a 38,000 to 42,000 molecular weight, the hydroxypropylmethylcellulose comprises a 9,200 to 11,300 molecular weight, and the expandable layer weighs 122 to 134 mg.

31. The dosage form according to claim 28 wherein, the cellulose acetate comprises a 39.8% acetyl content, and the polyethylene glycol comprises a 3,350 to 4,000 molecular weight.

32. The dosage form according to claim 28, wherein the membrane is a semipermeable wall and weighs 27 mg.

33. The dosage form according to claim 28, wherein the black iron oxide and the lactose are present as a 95:5 mix.

34. A dosage form comprising a drug layer that weighs 160 mg and comprises 20% hydromorphone hydrochloride, 74.68% poly(ethylene oxide) possessing a 200,000 molecular weight, 5% poly(vinylpyrrolidone), 0.02%



butylated hydroxytoluene, and 0.25% magnesium stearate; an expandable layer comprising 63.672% poly(ethylene oxide) possessing a 2,000,000 molecular weight, 30.00% sodium chloride, 5% hydroxypropylmethylcellulose, 1% black iron oxide and lactose, 0.25% magnesium stearate, and 0.05% butylated hydroxytoluene; a rate controlling membrane that surrounds both layers and comprises 99% cellulose acetate and 1% polyethylene glycol; and an exit in the membrane for delivering the drug from the dosage form.

35. The dosage form according to claim 34 wherein, the drug layer comprises 0.05% ferric oxide yellow.

36. The dosage form according to claim 34 wherein, the poly(vinylpyrrolidone) possesses a 38,000 to 42,000 molecular weight, the hydroxypropylmethylcellulose, and the expandable layer weighs 114 to 126 mg.

37. The dosage form according to claim 34 wherein, the cellulose acetate comprises an acetyl content of 39.8% and the polyethylene glycol comprises a 3,350 to 4,000 molecular weight.

38. The dosage form according to claim 34 wherein, the membrane is a semipermeable wall and weighs 29 mg.

39. The dosage form according to claim 34 wherein, the black iron oxide and lactose comprise a 95:5 mix and is a colorant.

40. A dosage form comprising a drug layer that weighs 213.3 mg and comprises 30% hydromorphone hydrochloride, 64.73% poly(ethylene oxide) possessing a 200,000 molecular weight, 5% poly(vinylpyrrolidone), 0.02% butylated hydroxytoluene and 0.25% magnesium stearate; an expandable layer comprising 64.3% poly(ethylene oxide) possessing a 2,000,000 molecular weight, 30.003% sodium chloride, 5% hydroxypropylmethyl-cellulose, black iron oxide and lactose, 0.25% magnesium stearate, and 0.05% butylated hydroxytoluene; a membrane that surrounds the layers and comprises 99% cellulose acetate and 1% polyethylene glycol; and an exit in the membrane for delivering the hydromorphone from the dosage form.

41. The dosage form according to claim 40, wherein the dosage form comprises 0.4% or 1% black iron oxide and 0.05% butylated hydroxytoluene.

42. The dosage form according to claim 40 wherein, the poly(vinylpyrrolidone) comprises a 38,000 to 42,000 molecular weight, the hydroxypropylmethylcellulose comprises a 9,200 to 11,300 molecular weight and the expandable layer weighs 156 to 172 mg.